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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,128	08/29/2005	Bronislava Gedulin	54061.8101.US00	7370

44638 7590 01/19/2007

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EXAMINER	
LI, RUIXIANG	
ART UNIT	PAPER NUMBER
1646	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/19/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/518,128	GEDULIN ET AL.	
	Examiner	Art Unit	
	Ruixiang Li	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 November 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5-12 and 14-21* is/are pending in the application.

4a) Of the above claim(s) *7 and 15-21* is/are withdrawn from consideration.

5)☒ Claim(s) *1-3, 5, 6, 8-12, and 14* is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application, Amendments, and/or Claims

Applicants' amendment filed on 11/14/2006 has been entered in full. Claim 1 has been amended. Claim 13 has been canceled. Claims 1-3, 5-12, and 14-21 are pending. Claims 1-3, 5, 6, 8-12, and 14 are under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Withdrawn Objections and/or Rejections

The rejection of claims 1, 10, and 14 under 35 U.S.C. 102(b) as being anticipated by Yoshinaga et al. (*Am. J. Physiol.* 263:G695-701, 1992) has been withdrawn in view of the claims, which limit the subject to a human.

Applicants' cancellation of claim 13 has made all the rejections related to the claim moot.

Claim Rejections Under 35 U.S.C.§112, 1st Paragraph (Written Description)

The rejections of claims 1-3, 5, 6, and 8-12 under 35 U.S.C. § 112, 1st paragraph for written description is maintained.

Applicants refer to the specification at pages 18 to 28 and argue that the specification provides numerous PYY agonist and analog species that are representative of the claimed genus.

Applicants' argument has been fully considered, but is not deemed to be persuasive for the following reasons. The specification defines PYY as a peptide YY polypeptide obtained or derived from any species, and defines PYY agonist as any compound which elicits an effect of PYY to protect from or reduce colon injury associated with inflammatory bowel disease or ulcerative colitis and which binds specifically in a Y receptor assay or in a competitive binding assay (page 10). Thus, the claims are drawn to a method comprising administration of PYY or a genus of structurally undefined PYY agonists. The specification at page 21, line 8 to page 22, line 10 provides general information on how to generate PYY mutants by deletion, substitution, and insertion, they are limited to peptide mutants of PYY. However, the PYY encompassed by the claims are not limited to the peptide PYY mutants. Thus, the disclosed species are not representative of the entire genus. Moreover, methods of identifying PYY agonists as disclosed at pages 24-28 of the specification are not equivalent to the methods of making a PYY agonist because they do not provide the information on the conserved structure critical for the PYY activity.

Applicants argue that written description support for the claimed species can be found in the numerous patent and journal articles that are incorporated by reference in the

specification. This is not found to be persuasive because while the prior art teaches numerous PYY agonists, these PYY agonists are still not representative of the entire genus recited in the instant claims because the PYY agonists encompass, as noted above, any compound which elicits an effect of PYY to protect from or reduce colon injury associated with inflammatory bowel disease or ulcerative colitis and which binds specifically in a Y receptor assay or in a competitive binding assay. Secondly, not all the prior patents or journal articles teach PYY agonists in the same context of treating intestinal damage.

Applicants argue that Applicants have provided sufficient guidance and working examples as to structural and functional characterization of the claimed PYY agonists, e.g., through extensive disclosure of PYY analog sequences, and/or assays for verifying PYY activity. Applicants submit that PYY agonists and agonist analogs, including derivatives, are sufficiently described in the specification to reasonably convey to one of ordinary skill in the art that the inventors, at the time the application was filed, had possession of the claimed invention.

Applicants' argument has been fully considered, but is not deemed to be persuasive because the specification fails to provide any critical structural feature to adequately describe the genus of PYY agonists that may be administered in the claimed method. There is no defined relation between function and structure of the PYY agonists. There is even no identification of any particular portion of the structure that must be

conserved. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the genus of PYY agonists.

Claim Rejections Under 35 U.S.C.§102 (a)

The rejection of claims 1-3, 5, 10, and 13 under 35 U.S.C. 102(a) as being anticipated by El-Salhy et al. (Peptides 23:397-402, February 2002) is maintained.

Applicants argue that El-Salhy et al. do not teach administration of PYY or PYY agonists to a subject, let alone a human. Applicants further argue that El-Salhy et al. do not teach or fairly suggest administering PYY to any subject in order to treat intestinal damage.

Applicants' argument has been fully considered, but is not deemed to be persuasive for the following reasons. As noted in the previous office action, El-Salhy et al. teach a decreased level of PYY in human patients with gastrointestinal disorders, including inflammatory bowel diseases (examples are Crohn's colitis and ulcerative colitis; pages 398-399). El-Salhy et al. also teach that the changes in PYY in gastrointestinal disorders could be beneficial in clinical practice and that in cases where PYY increase is desirable, diet that increases PYY synthesis and release can be followed, or a receptor agonist can be utilized (Abstract; page 401). El-Salhy et al. further teach that infusion of PYY in dogs increases colonic absorption of water, Na and Cl ions and PYY or its analogue can be of use as clinical agents in intestinal malabsorption disorders or after

bowel resection (page 401). Accordingly, El-Salhy et al. do teach administration of PYY or PYY agonists to a subject, including a human to treat intestinal damage.

Claim Rejections Under 35 U.S.C.§102 (b)

The rejection of claims 1, 2, 5, and 10-12 under 35 U.S.C. 102(b) as being anticipated by Balasubramaniam (U. S. Patent No. 5,604,203, Feb. 18, 1997) is maintained.

Applicants argue that Balasubramaniam does not or even fairly suggest administering PYY or a PYY agonist to a human. Applicants further argue that Balasubramaniam does not teach or fairly suggest administering PYY to a subject in order to treat intestinal damages.

Applicants' argument has been fully considered, but is not deemed to be persuasive because Balasubramaniam clearly teaches administering PYY or a PYY agonist to a human (see, e.g., lines 45-46, column 6). Moreover, Balasubramaniam teaches treating gastrointestinal disorders, especially infectious or inflammatory diarrhea, or diarrhea resulting from surgery (column 16). Inflammatory diarrhea includes Crohn's disease (column 7), a form of inflammatory bowel disease, with PYY and its analogues (column 7). Thus, Balasubramaniam teaches administering PYY to a subject to treat intestinal damages associated with these diseases.

Claim Rejections Under 35 U.S.C.§103 (a)

(i). The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

(ii). Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Balasubramaniam (U. S. Patent No. 5,604,203, Feb. 18, 1997), as applied to claims 1, 2, 5, and 10-12 above, and further in view of Dumont et al. (Brain Res. Mol. Brain Res. 26: 320-324, 1994).

Balasubramaniam teaches a method of treating an intestinal damage comprising administering a pharmaceutically active formulation of PYY or a PYY agonist to a human subject as applied to claims 1, 2, 5, and 10-12 above.

Balasubramaniam fails to teaches the method of claim 14, comprising administering PYY[3-36].

Dumont et al. teach a PYY agonist, PYY[3-36] that binds PYY receptors (see Abstract).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use a PYY agonist, PYY[3-36], in the method of treating a gastrointestinal disorder, such as Crohn's disease (a form of inflammatory bowel) as

taught by Balasubramaniam with a reasonable expectation of success. One would have been motivated to do so because Balasubramaniam teaches PYY and PYY agonists can be used to treat a gastrointestinal disorder, such as Crohn's disease, whereas PYY [3-36], which binds to PYY receptors, is expected to have the same effect in treating a gastrointestinal disorder, such as Crohn's disease.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (571) 272-0875. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on (571) 272-0835. The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, please contact the Electronic Business Center (EBC) at the toll-free phone number 866-217-9197.

Ruixiang Li

Ruixiang Li, Ph.D.
Primary Examiner
January 10, 2007

RUIXIANG LI, PH.D.
PRIMARY EXAMINER